

FORM PTO-1390
OFFICE
(Modified)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK

ATTORNEY'S DOCKET NUMBER
32860-01079/US

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/589535

EXPRESS MAIL LABEL NO.

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

INTERNATIONAL APPLICATION NO.

PCT/EP2005/050517

INTERNATIONAL FILING DATE

February 7, 2005

PRIORITY DATE CLAIMED

February 18, 2004 and
October 28, 2004

TITLE OF INVENTION

METHOD FOR CONDUCTING A CLINICAL STUDY

APPLICANT(S) FOR DO/EO/US


Klaus ABRAHAM-FUCHS, Rainer KUTH, Eva RUMPEL, Markus SCHMIDT, Siegfried SCHNEIDER, Horst SCHREINER, Gudrun ZAHLMANN

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)) **WO 2005/081162 A2**
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is transmitted herewith.
 - b. ☒ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 20. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98-1449, International Search Report (PCT/ISA/210) in English and PTO Form 1449 listing 5 & submitting 4 ref.'s, ISR, German OA
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☒ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: 2 sheets of Formal Drawings, Written Opinion (PCT/ISA/237)

U.S. APPLICATION NO (if known, see 37 CFR 1.5) 10/589535		INTERNATIONAL APPLICATION NO PCT/EP2005/050517		ATTORNEY'S DOCKET NUMBER 32860-01079/US	
21. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
PCT FEES – NATIONAL STAGE:					
<u>Fee Code</u>	<u>Description</u>	<u>Fee</u>			
1631	Basic National Stage Fee.....	\$300.00			
1632	National Stage Search Fee..... (Search report prepared and provided to USPTO)	\$400.00			
1633	National Stage Examination Fee.....	\$200.00			
ENTER APPROPRIATE FEE AMOUNT =				\$ 900.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 Months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
PAGES	PAGES FILED	EXTRA PAGES FILED IN 50 PAGE SEGMENTS	RATE		
Total Pages	21 - 100 =	0	X 250.00	\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	17 - 20 =	0	X \$50.00	\$	
Independent Claims	2 - 3 =	0	X \$200.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360.00	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 900.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 900.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 Months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$ 900.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$ 40.00	
TOTAL FEES ENCLOSED =				\$ 940.00	
				Amount to be: refunded	\$
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$940.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account. No. 08-0750 in the amount of \$ to cover the above fees. A triplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-0750</u> .					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
Send all correspondence to: Harness, Dickey & Pierce, P.L.C – Customer No. 30596 Post Office Box 8910 Reston, Virginia 20195					
Date: August 16, 2006			By <u></u> Donald J. Daley, Reg. No. 34,313		
DJD/jap					